

October 4, 2004

Mark McClellan, MD
Administrator
Centers for Medicare & Medicaid Services
Washington, DC 20201

File Code: CMS-4068-P

Dear Dr. McClellan:

The American Health Quality Association (AHQA), representing the national network of Medicare Quality Improvement Organizations (QIOs), is pleased to be able to provide these comments on the proposed rule to establish the Medicare outpatient prescription drug benefit. The size of the proposed regulation can't begin to adequately measure the enormous complexity of implementing the provisions of Medicare Modernization Act (MMA). The dedicated staff at the Centers for Medicare & Medicaid Services (CMS) is to be commended for their efforts to move forward expeditiously with implementation of the law. I hope that AHQA's comments will be useful in that endeavor.

Our comments and suggestions are grouped and labeled as requested in the Federal Register notice published on August 3, 2004.

General Provisions

Quality Assurance Requirements (§ 423.153(c))

Recommendation: The regulation should explicitly encourage Prescription Drug Plans (PDPs) and Medicare Advantage Prescription Drug plans (MA-PD plans) to coordinate and work directly with QIOs as a way to meet requirements for educational interventions, Medication Therapy Management and other quality improvement efforts targeted at providers, practitioners and beneficiaries.

AHQA strongly supports language in the narrative encouraging PDPs and MA-PD plans to work with QIOs on these activities. This will reduce the level of burden on plans, providers and practitioners to engage in efforts to improve the quality of prescription drug therapy. A number of plans participating in coordinated activities could contribute to achieving more widespread success in improving care across a region.

Quality Improvement Organization (QIO) Activities (§ 423.162)

Recommendation: AHQA suggested in its September 20, 2004 comments on the Summary of the QIO 8th Scope of Work (SOW8) that CMS should embrace a of number principles as it develops the QIO work related to the new drug benefit:

- Most drug-related problems in the elderly probably involve medications that are not on anybody's "bad drug" list.

- A focus on simply reducing the total number of drugs that an older patient receives may be a misguided approach to quality improvement.
- Quality-improvement efforts should focus on specific classes of drugs or specific medical conditions.
- Physicians, with the help of QIOs, need to figure out better ways to work together with clinical pharmacists.
- CMS and the QIOs should use methods such as academic detailing, proven effective and cost-effective repeatedly in randomized controlled studies --
 - Soumerai & Avorn (1986): \$2 saving for each \$1 spent on program
 - Silagy, May & Avorn (1997): Academic detailing based services in some therapeutic topics within ongoing service-based programs, direct cash savings can exceed costs by a ratio of 6 to 1
 - Mason, Freemantle et al (2001): Even with small overall effect sizes academic detailing can be cost effective.

Recommendation: CMS must ensure that QIOs have access to the necessary data to perform the quality improvement functions envisioned in Section 109 of the MMA. The provider and pharmacy identifiers described in the narrative will be absolutely critical to these activities. The agency should create a Technical Expert Panel, with representation from the QIO community and others, to examine what data elements will be necessary for prescription drug quality improvement.

Recommendation: Create an exception to the information disclosure regulation at 42CFR Part 480 to permit QIOs to notify a patient's physician when a threat to patient safety is identified by the QIO.

The value and credibility of the QIO's quality improvement assistance to the plans and prescribers will be greatly enhanced if the QIO is able to timely notify the patient's physician(s) of patient safety issues that are suggested by the QIO's quality studies. At present, the QIO can know the details of these problems but is prohibited from telling the patient's physician because other physicians' treatments or actions may be thereby disclosed. We believe that protecting the patient's health and safety is the ultimate priority in the quality measurement and improvement system, and that such notifications must be transmitted or telephoned to appropriate physician(s), with appropriate caveats indicating that the perceived problem may in fact be something of which the patient and physician are already aware.

CMS is right to be concerned that there may be occasional objections to the sharing of such information with a patient's physician, but the notification process has safeguards built into it. A patient's physician may be assumed to be a safe custodian of personal information and certainly may be assumed to have the patient's interests in the forefront of their thinking when they are informed of the patient possibly being at risk. If the Medicare program were to collect information on such threats to patient safety (e.g., patients on high risk medications without any sign of appropriate lab work to ensure safe use of the drug) and NOT tell the physician(s) involved in the care of the patient, CMS must anticipate severe criticism for not exercising its role as a responsible steward of the patient's interest.

Requirements for Disclosure of Information (§ 423.322)

Recommendation: CMS should ensure that prescription transaction data, including the name of the prescriber with as much accuracy as possible, is made available on a timely basis to the QIOs.

Without this information, it will be extremely difficult for QIOs to execute the direction of Congress in section 109 of the MMA, where the law directs QIOs to offer assistance to practitioners and plans for the purpose of improving the quality of pharmacotherapy received by older and disabled Americans enrolled in the Medicare outpatient drug benefit. Because of the sophistication of the pharmacy and drug benefits management industries, today virtually all prescription drug claims are adjudicated online, real-time. QIOs must have timely data, but need not have real-time data. Some element of burden on PDPs and MA plans can be relieved by CMS arranging to receive batches of transaction data biweekly or perhaps monthly.

Recommendation: CMS should ensure there are no barriers to QIOs being able to link Part D transaction data to Part A and Part B claims as part of quality improvement efforts.

AHQA strongly agrees with CMS that the prescription drug data should be collected in such a way that it is linkable with other data. The QIOs should be able to link these claims back to beneficiaries and prescribers, as well as plans, to identify prescribing issues that threaten the health and safety of Medicare enrollees. Examples of uses for such linkages and analyses include:

- Identifying plans and prescribers which have patients receiving warfarin therapy who are not receiving timely concomitant INR testing.
- Identifying plans, prescribers and hospitals which have patients discharged for heart attack or congestive heart failure but who appear not to be receiving beta blocker and ACE inhibitor therapy.

Subpart M-Grievances, Coverage Determinations, Reconsiderations, and Appeals

Recommendation: CMS should consider using the QIOs to perform expedited independent external appeals related to the drug benefit.

The QIOs have proven ability, through their handling of beneficiary fast-track appeals of termination of service and discharge notices, to respond quickly in making complex medical necessity determinations. They have significant experience evaluating published evidence and relating it to physicians' clinical decision making. Utilizing the QIOs in a similar role with prescription drug appeals would provide a consistent appeal mechanism that is familiar to and trusted by physicians and beneficiaries.

If the plan regions are ultimately mostly confined to individual states, then it will be important for the external appeal entities to have a good understanding of the formularies in use by the plans in the regions. The formularies may vary a fair amount across the regions in response to competition among the plans within the individual regions and the makeup of

the beneficiary population. This argues in favor of a contractor with an in-depth knowledge of the plans and the physician practice norms in the region.

Recommendation: There should be a national outreach effort to inform beneficiaries and physicians of these appeal rights.

The QIOs already undertake educational efforts regarding beneficiary appeal rights, and CMS could take advantage of the existing QIO role with appeals to educate beneficiaries and physicians about the new appeal rights available under the drug benefit.

Recommendation: The beneficiary should be given at least a three day supply of the medication prescribed by his or her physician during the time an appeal is being evaluated.

We believe this is the standard under Medicaid law and will provide a necessary safeguard for beneficiaries during the appeal process.

I appreciate the opportunity to offer these recommendations for your consideration in developing the final rule for the prescription drug benefit. Please contact me if I can answer any questions or provide additional information.

Sincerely,

David G. Schulke
Executive Vice President